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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,557	08/18/2000	Brydon L. Bennett	10624-046-999	6892
20583	7590	04/10/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/642,557

Applicant(s)

BENNETT ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 24-35, 38, 40-54 and 56 is/are pending in the application.
- 4a) Of the above claim(s) 28-33 and 40-46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 and 56 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 25-27, 34, 35, 38 and 47-54 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1626

**DETAILED ACTION**

Claims 1-8, 24-35, 38, 40-54 and 56 are pending in the application.

***Election/Restrictions***

During a telephone conversation with Mr. Michael Bruner on July 6, 2004, a provisional election was made with traverse to prosecute the invention of Group I (drawn to products). The requirement was deemed proper and made FINAL in a previous Office Action.

Claims 28-33 and 40-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants'

Art Unit: 1626

amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-8, 25, 27, 34, 35, 38 and 47-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

Art Unit: 1626

unpatentable over claims 16-18 and 21-23 of copending Application No. 10/395,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically described in the copending application.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, asthma. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

Art Unit: 1626

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicants' arguments filed January 20, 2006 have been fully considered. Applicants argue that, upon entry of the presently made amendments, all other outstanding issues would have been overcome and therefore, the double patenting rejection should be withdrawn per M.P.E.P. §804(I)(B). In response, the rejection of the claims under 35 U.S.C. 103(a) has not been overcome and therefore, the double patenting rejection is maintained.

Art Unit: 1626

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 26, 27, 52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showalter et al. {U.S. Pat. 4,556,654}.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicants claim pyrazoloanthrone compounds. Showalter et al. (column 1; column 21, lines 38-62; column 35, lines 64-68; columns 39-42; and especially the 1<sup>st</sup>, 6<sup>th</sup> and 8<sup>th</sup> compounds in columns 25-26) teach pyrazoloathrone compounds that are structurally similar to the instant claimed compounds.

Art Unit: 1626

*Ascertainment of the difference between the prior art and the claims*

*(MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP*

*§2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-tumor agent).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which



Art Unit: 1626

would be useful, for example, in treating tumors.

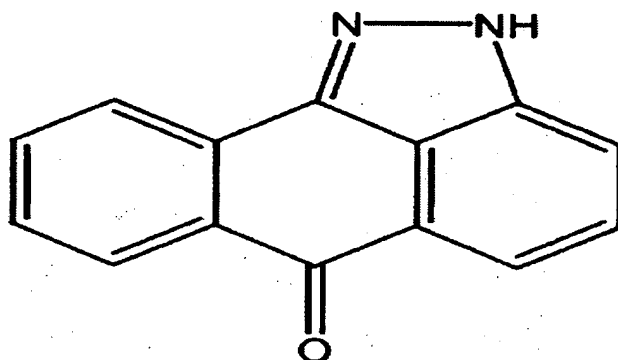
Absent a side-by-side showing of unexpected, beneficial and superior results, the instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### ***Response to Arguments***

Applicants' arguments filed January 20, 2006 have been fully considered. Applicants argue that peer-reviewed literature publication by Bennett et al. (PNAS, November 20, 2001, Vol. 98, No. 24, pages 13681-13686) sets forth comparative data demonstrating unexpected superior biological activity of N-unsubstituted compounds {SP600125} relative to N-2 substituted compounds. Applicants argue that the N-2 unsubstituted compounds (i.e., SP600125, Compound D and Compound E), which are shown in Figure 1, page 13682 in column 2 (reproduced below), have superior JNK

Art Unit: 1626

inhibitory activity relative to N-2 substituted compounds (i.e., Compounds A-C). Applicants further argue that Bennett et al. (page 13683, first full paragraph) also teach the importance of the free NH group in the pyrazoloanthrone core structure of the presently claimed compounds.

**a****b**

Compound	Structure	JNK2, $\mu\text{M}$	JNK3, $\mu\text{M}$
SP600125		0.11	0.19
Compound A		18	24
Compound B		6	7
Compound C		3.0	6.1
Compound D		0.05	0.11
Compound E		0.18	0.43

**Fig. 1.** Characterization of SP600125. (a) Chemical structure. (b) Structure-activity relationship study of anthrapyrazolones ( $\text{IC}_{50}$  values).

Art Unit: 1626

Applicants' arguments have been considered but have not been found persuasive. The compounds found in Bennett et al. embrace neither the instant claimed compounds nor any of the compounds of Showalter et al. Applicant relying upon comparative showing to rebut *prima facie* case must compare his claimed invention with the closest prior art. In re Holladay, 199 USPQ 516, 1978. Further, Bennett et al. (page 13683, first full paragraph) teach that the placement of a chlorine atom on different positions of the anthrapyrazolone core also affects the activity. Since a substituent is required on the anthrapyrazolone core in instant independent claims 3, 26 and 27, one skilled in the art would not know if the JNK activity is increased or decreased by the presence of these substituents (i.e., nitro and aminoalkoxy as found in claim 3; a group -NH-(alkyl)-NR<sub>3</sub>R<sub>4</sub> as found in claim 26; and -NH-Y(O)<sub>n</sub>-R<sub>6</sub> as found in claim 27) required by the instant claims. Therefore, the rejection of the claims is maintained.

***Allowable Subject Matter***

Claims 4 and 5 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 24 and 56 are allowed over the art of record.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed

Art Unit: 1626

until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 28-33 and 40-46 drawn to an invention nonelected with traverse in telephone conversation of July 6, 2004. A complete reply, if any, to the final rejection must include cancellation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

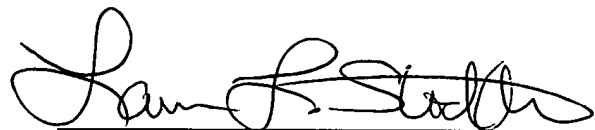
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is

Art Unit: 1626

(571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

April 4, 2006